

Department of Health and Human Services Public Health Service Small Business Technology Transfer Program Phase II Grant Application <i>Follow instructions carefully.</i>		Leave blank — for PHS use only. <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">Type</td> <td style="width: 33%;">Activity</td> <td style="width: 33%;">Number</td> </tr> <tr> <td>Review Group</td> <td colspan="2">Formerly</td> </tr> <tr> <td colspan="2">Council Board (Month, year)</td> <td>Date Received</td> </tr> </table>		Type	Activity	Number	Review Group	Formerly		Council Board (Month, year)		Date Received
Type	Activity	Number										
Review Group	Formerly											
Council Board (Month, year)		Date Received										
1a. TITLE OF APPLICATION (<i>Do not exceed 56 typewriter spaces</i>)		1b. Phase I Grant No.										
2. PRINCIPAL INVESTIGATOR												
2a. NAME (<i>Last, first, middle</i>)		2b. DEGREE(S)										
		2c. SOCIAL SECURITY NO. Provide on Personal Data Page.										
2d. POSITION TITLE		2e. MAILING ADDRESS (<i>Street, city, state, zip code</i>)										
2f. TELEPHONE AND FAX (<i>Area code, number, and extension</i>) TEL: FAX:		BITNET/INTERNET Address:										
3. HUMAN SUBJECTS	3a. If "yes," Exemption no. <input type="checkbox"/> or <input type="checkbox"/> IRB approval date <input type="checkbox"/>	3b. Assurance of compliance no. <input type="checkbox"/>	4. VERTEBRATE ANIMALS									
<input type="checkbox"/> NO <input type="checkbox"/> YES	<input type="checkbox"/> Full IRB or Expedited Review	<input type="checkbox"/> NO <input type="checkbox"/> YES	4a. If "Yes," IACUC approval date <input type="checkbox"/> 4b. Animal welfare assurance no. <input type="checkbox"/>									
5. DATES OF ENTIRE PROPOSED PHASE II PERIOD <i>From:</i> <i>Through:</i>	6. COSTS REQUESTED FOR FIRST 12-MONTH BUDGET PERIOD 6a. Direct Costs \$ 6b. Total Costs \$		7. COSTS REQUESTED FOR ENTIRE PROPOSED PHASE II PERIOD 7a. Direct Costs \$ 7b. Total Costs \$									
8. PERFORMANCE SITES (<i>Organizations and addresses</i>)		9. APPLICANT ORGANIZATION (<i>Name and address of applicant small business concern</i>)										
		10. ENTITY IDENTIFICATION NUMBER Congressional District										
11. INVENTIONS AND PATENTS <input type="checkbox"/> NO <input type="checkbox"/> YES If "Yes," <input type="checkbox"/> Previously reported OR <input type="checkbox"/> Not previously reported		12. SMALL BUSINESS CERTIFICATION <input type="checkbox"/> Small Business Concern <input type="checkbox"/> Women-owned <input type="checkbox"/> Socially and Economically Disadvantaged										
13. NOTICE OF PROPRIETARY INFORMATION: The information identified by asterisks(*) on pages _____ of this application constitutes trade secrets or information that is commercial or financial and confidential or privileged. It is furnished to the Government in confidence with the understanding that such information shall be used or disclosed only for evaluation of this application, provided that, if a grant is awarded as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information herein to the extent provided by law. This restriction does not limit the Government's right to use the information if it is obtained without restriction from another source.		15. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION Name: Title: Address: Telephone: FAX: BITNET/INTERNET Address:										
14. DISCLOSURE PERMISSION STATEMENT: If this application does not result in an award, is the Government permitted to disclose the title only of your proposed project, and the name, address, and telephone number of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information or possible investment? <input type="checkbox"/> YES <input type="checkbox"/> NO												
16. PRINCIPAL INVESTIGATOR ASSURANCE: I certify that the statements herein are true, complete, and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.		SIGNATURE OF PERSON NAMED IN 2a (<i>In ink. "Per" signature not acceptable.</i>)	DATE									
17. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete, and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Service terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.		SIGNATURE OF PERSON NAMED IN 15 (<i>In ink. "Per" signature not acceptable.</i>)	DATE									

Abstract of Research Plan

NAME, ADDRESS, AND TELEPHONE NUMBER OF APPLICANT ORGANIZATION

YEAR FIRM FOUNDED

NO. OF EMPLOYEES (*include all affiliates*)

TITLE OF APPLICATION

KEY PERSONNEL ENGAGED ON PROJECT

NAME	ORGANIZATION	ROLE ON PROJECT
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ABSTRACT OF RESEARCH PLAN: State the application's broad, long-term objectives and specific aims, making reference to the health-relatedness of the project. Describe concisely the research design and methods for achieving these goals and discuss the potential of the research for technological innovation. Avoid summaries of past accomplishments and the use of the first person. This abstract is meant to serve as a succinct and accurate description of the proposed work when separated from the application. If the application is funded, this description, as is, will become public information. ***Therefore, do not include proprietary or confidential information.*** DO NOT EXCEED 200 WORDS.

Provide key words (8 maximum) to identify the research or technology.

Provide a brief summary of the potential commercial applications of the research.

Small Business Technology Transfer Program Phase II Grant Application Table of Contents

Number pages consecutively at the bottom throughout the application. Do not use suffixes such as 5a, 5b. Type the name of the Principal Investigator at the top of each printed page and each continuation page.

	<i>Page Numbers</i>
Face Page, Abstract, Table of Contents	1–3
Detailed Budget of Applicant Organization for First 12-Month Budget Period—Direct Costs Only	4
Budget of Applicant Organization for Entire Proposed Phase II Period—Direct Costs Only	5
Detailed Budget of Research Institution for First 12-Month Budget Period	6
Budget of Research Institution for Entire Proposed Phase II Period	7
Budgets Pertaining to Other Contractual Arrangements	_____
Biographical Sketch—Principal Investigator (<i>Not to exceed two pages</i>)	_____
Other Biographical Sketches (<i>Not to exceed two pages for each</i>)	_____
Other Support	_____
Resources	_____

Research Plan

Introduction to Revised Application (<i>Not to exceed three pages</i>)	_____
1. Specific Aims	_____
2. Significance	_____
3. Phase I Final Report (<i>Recommended not to exceed ten pages</i>)	_____
4. Experimental Design and Methods	_____
5. Human Subjects	_____
6. Vertebrate Animals	_____
7. Consultants	_____
8. Consortium Arrangements	_____
9. Literature Cited	_____
Checklist	_____

*Type density and type size of the entire application must conform to limits provided in application instructions under "Type Size."

Appendix (*Three sets. No page numbering necessary for Appendix.*)

Number of publications and manuscripts accepted for publication (*Not to exceed ten*): _____

Other items (*list*): _____

Detailed Budget of Applicant Organization for First 12-Month Budget Period—Direct Costs Only					FROM	TO	
PERSONNEL <i>(Applicant organization only)</i>		Type Appt. <i>(months)</i>	% Effort on Project	Institutional Base Salary	DOLLAR AMOUNT REQUESTED <i>(omit cents)</i>		
NAME	Role on Project				Salary Requested	Fringe Benefits	TOTALS
SUBTOTALS →							
CONSULTANT COSTS							
EQUIPMENT <i>(Itemize)</i>							
SUPPLIES <i>(Itemize by category)</i>							
TRAVEL							
PATIENT CARE COSTS		Inpatient					
		Outpatient					
ALTERATIONS AND RENOVATIONS <i>(Itemize by category)</i>							
CONTRACTUAL COSTS							
OTHER EXPENSES <i>(Itemize by category)</i>							
TOTAL DIRECT COSTS FOR FIRST 12-MONTH BUDGET PERIOD <i>(Also enter on Face Page, Item 6a)</i> →					\$		
FIXED FEE REQUESTED					\$		

Budget of Applicant Organization for Entire Proposed Phase II Period—Direct Costs and Fixed Fee

BUDGET CATEGORY TOTALS		FIRST BUDGET PERIOD (from Page 4)	SECOND BUDGET PERIOD	THIRD BUDGET PERIOD (if necessary)
PERSONNEL <i>(Salary and fringe benefits)</i> <i>(Applicant organization only)</i>				
CONSULTANT COSTS				
EQUIPMENT				
SUPPLIES				
TRAVEL				
PATIENT CARE COSTS	INPATIENT			
	OUTPATIENT			
ALTERATIONS AND RENOVATIONS				
CONTRACTUAL COSTS				
OTHER EXPENSES				
Total Direct Costs				

**Total Direct Costs for
Entire Proposed Phase II Period** *(Also enter on Face Page, Item 7a)* —————→

\$

JUSTIFICATION: Describe the specific functions of the personnel and consultants. For ALL years, justify any unusual items such as major equipment, foreign travel, alterations and renovations, patient care costs, and contractual costs. Identify with an asterisk any significant increases or decreases from the first budget period and explain and justify all categories marked with an asterisk. Justify any request that exceeds the overall STTR Phase II limitations of cost (\$500,000) and period of support (two years). Use continuation page(s) if necessary.

BUDGET CATEGORY TOTALS	FIRST BUDGET PERIOD (from Page 4)	SECOND BUDGET PERIOD	THIRD BUDGET PERIOD (if necessary)
Fixed Fee Requested			

**Total Fixed Fee Requested for
Entire Proposed Phase II Period** *(Add to "total direct costs for entire proposed phase II period" above and "indirect costs for entire proposed phase II period" from Checklist [form page 11] and enter new total on Face Page, Item 7b.)* —————→

\$

**Detailed Budget of Research Institution for
First 12-Month Budget Period**

FROM: _____

TO: _____

NAME AND ADDRESS OF RESEARCH INSTITUTION _____

PERSONNEL		Type Appt. (months)	% Effort on Project	Institutional Base Salary	DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	Role on Project				Salary Requested	Fringe Benefits	TOTALS
SUBTOTALS →							
CONSULTANT COSTS							
EQUIPMENT (Itemize)							
SUPPLIES (Itemize by category)							
TRAVEL							
PATIENT CARE COSTS		Inpatient					
		Outpatient					
CONTRACTUAL COSTS							
OTHER EXPENSES (Itemize by category)							
TOTAL DIRECT COSTS							\$
INDIRECT COSTS (show calculation)							
TOTAL COSTS (Also enter as "Contractual Costs" on Budget of Applicant Organization—form page 4)							\$

CERTIFICATION OF RESEARCH INSTITUTION PARTICIPATION

Through the signature below of the duly authorized representative of the research institution on this budget page, and by way of the signature of the official signing for applicant organization (small business concern) on the Face Page of the application, the small business concern and the research institution certify jointly that: (1) the proposed STTR project will be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of the work will be performed by the research institution ("cooperative research and development"); (2) the proposed STTR project is a cooperative research or research and development effort to be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of

the work will be performed by the research institution ("performance of research and analytical work"); and (3) regardless of the proportion of the proposed project to be performed by each party, the small business concern will be the primary party that will exercise management direction and control of the performance of the project. If the research institution is a contractor-operated federally funded research and development center, the duly authorized representative of the contractor-operated federally funded research and development center certifies, *additionally*, that it: (4) is free from organizational conflicts of interests relative to the STTR program; (5) did not use privileged information gained through work performed for an STTR agency or private access to STTR agency personnel in the development of this STTR grant application; and (6) used outside peer review, as appropriate, to evaluate the proposed project and its performance therein.

SIGNATURE of duly authorized representative	Printed Name	Title	Date
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Budget of Research Institution for Entire Proposed Phase II Period

BUDGET CATEGORY TOTALS		FIRST BUDGET PERIOD <i>(from Page 4)</i>	SECOND BUDGET PERIOD	THIRD BUDGET PERIOD <i>(if necessary)</i>
PERSONNEL <i>(Salary and fringe benefits)</i>				
CONSULTANT COSTS				
EQUIPMENT				
SUPPLIES				
TRAVEL				
PATIENT CARE COSTS	INPATIENT			
	OUTPATIENT			
CONTRACTUAL COSTS				
OTHER EXPENSES				
Total Direct Costs				
Indirect Costs <i>(Show calculation for other than first budget period.)</i>				

Total Costs for Entire Proposed Phase II Period

(Also enter as "Contractual Costs" on Budget of Applicant Organization for Entire Proposed Phase II Period, Form Page 5.) _____ →

\$

JUSTIFICATION: Describe the specific functions of the personnel and consultants. For ALL years, justify any unusual items such as major equipment, foreign travel, patient care costs, and contractual costs. Identify with an asterisk any significant increases or decreases from the first budget period and explain and justify all categories marked with an asterisk.

Biographical Sketch

Provide the following information for the key personnel listed on Page 2, beginning with the Principal Investigator. Photocopy this page or follow this format for each person.

NAME	POSITION TITLE		
EDUCATION/TRAINING (<i>Begin with baccalaureate or other initial professional education. Include postdoctoral training.</i>)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR CONFERRED	FIELD OF STUDY

RESEARCH AND/OR PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, authors, and complete references to those publications most pertinent to this application. **DO NOT EXCEED TWO PAGES.**

Other Support

(Use continuation pages if necessary. Include the Principal Investigator's name at the top and number consecutively.)

FOLLOW INSTRUCTIONS CAREFULLY. Incomplete, inaccurate, or ambiguous information could lead to significant delays in the review and/or possible funding of this application. OTHER SUPPORT is defined as *all financial resources*, whether Federal, non-Federal, commercial, or institutional, *available in direct support of an individual's research endeavors*, including, but not limited to, research grants, cooperative agreements, contracts, and/or institutional awards. **DO NOT INCLUDE TRAINING AWARDS, PRIZES, OR GIFTS.**

Information on active and pending OTHER SUPPORT is required for **each** of the key personnel listed on Page 2, **excluding** consultants. Indicate "None" for individuals with no active or pending support. **DO NOT SUBMIT** a separate page for each person listed for whom "None" is indicated. List OTHER SUPPORT in two separate groups: (1) *all* currently active support, and (2) *all* applications and proposals pending review or funding (*do not include this application*). In a separate group, *list any other active or pending support to the applicant organization (small business concern) for work related to **this** project*. For all groups, specifically identify projects under the Small Business Innovation Research (SBIR) program and the Small Business Technology Transfer (STTR) program. If the support is provided under a subcontract arrangement or is part of a multi-project award, identify the principal investigator and provide the data below for both the parent and the subproject.

For each item, provide: (a) source of support, identifying number, title, and inclusive dates of the project as approved (for *active* awards) or proposed (for *pending* support); (b) brief statement of overall objectives of the project, subproject, or subcontract; (c) *annual* direct costs as approved or proposed; and (d) percentage of effort on the project. After listing all OTHER SUPPORT, summarize for each individual any potential overlap with active or pending projects and *this* application in terms of the science, budget, or an individual's committed effort. (See instructions for definitions of the three types of overlap.) Any necessary resolution of overlap due to this application being funded will occur in conjunction with the applicant organization and the Public Health Service awarding component staff at the time of award.

Resources

FACILITIES: Specify the facilities to be used for the conduct of the proposed research. (The research to be performed by the applicant small business concern and its collaborators must be in facilities that are available to and under the control of each party for the conduct of each party's portion of the proposed project.) Indicate the facilities at the applicant small business concern and any other performance site listed on the FACE PAGE where the facilities are located and describe their capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Under "Other," identify support services such as secretarial, machine shop, electronics shop, and the extent to which they will be available to the project. Use continuation page(s) if necessary.

Laboratory:

Clinical:

Animal:

Computer:

Office:

Other:

MAJOR EQUIPMENT: List the most important equipment items already available for this project, noting the location and pertinent capabilities of each.

Checklist

TYPE OF APPLICATION (Check appropriate box(es).)

- ☐ NEW application. (This application is being submitted to the Public Health Service for the first time.)
- ☐ REVISION of previously-submitted application number _____
(This application replaces a prior unfunded version of a new application.)
- ☐ CHANGE of Principal Investigator (if applicable)
Name of former Principal Investigator _____

1. ASSURANCES/CERTIFICATIONS

The assurances/certifications set forth below are made and verified by the signature of the OFFICIAL SIGNING FOR APPLICANT ORGANIZATION (small business concern) on the FACE PAGE of the application. Descriptions of individual assurances/certifications are found in application instructions under "Checklist." If unable to certify compliance with any item, provide an explanation and place it after this page.

• Human Subjects; • Vertebrate Animals; • Debarment and Suspension; • Drug-Free Workplace; • Lobbying; • Delinquent Federal Debt; • Research Misconduct; • Civil Rights (Form HHS 690); • Handicapped Individuals (Form HHS 690); • Age Discrimination (Form HHS 690); • Financial Conflict of Interest.

2. PROGRAM INCOME (See discussion in application instructions under "Checklist.")

All applications must indicate (Yes or No) whether program income is anticipated during the period for which grant support is requested.

- ☐ No ☐ Yes (If "Yes," use the format below to reflect the amount and source(s) of anticipated program income.)

Budget Period	Anticipated Amount	Source(s)

3. INDIRECT COSTS (See discussion in application instructions under "Checklist.")

Insert the rate, if known. If the applicant organization does not have a currently negotiated rate with the Department of Health and Human Services (DHHS) or another Federal agency, it must estimate the amount of indirect costs allocable (applicable) to the proposed Phase II project. That amount should be inserted in the space provided below. The

applicant organization should also be prepared to furnish financial documentation to support the estimated amount, if requested by the Public Health Service. An applicant organization may elect to waive indirect costs if it so desires.

- ☐ DHHS agreement, dated: _____ ☐ No indirect costs requested.
- ☐ No DHHS agreement, but rate established with _____, dated: _____
- ☐ Rate negotiation pending with the National Institutes of Health.

CALCULATION*

(The entire grant application, including the Checklist, will be reproduced and provided to peer reviewers as CONFIDENTIAL information. Supplying the following information on indirect costs is OPTIONAL.)

a. First 12-month budget period:

Amount of base \$ _____ x Rate applied _____ % = indirect costs (1) \$ _____

b. Entire proposed Phase II period:

Amount of base \$ _____ x Rate applied _____ % = indirect costs (2) \$ _____

(1) Add to "total direct costs" and "fixed fee requested" from form Page 4 and enter new total on Face Page, Item 6b.

(2) Add to "total direct costs" and "fixed fee requested" from form Page 5 and enter new total on Face Page, Item 7b.

*Check appropriate box(es):

- ☐ Salary and wages base ☐ Modified total direct costs base ☐ Other base (Explain on separate page.)
- ☐ Off-site, other special rate, or more than one rate involved (Explain on separate page.)

4. SMOKE-FREE WORKPLACE

Does your organization currently provide a smoke-free workplace and/or promote the non-use of tobacco products or have plans to do so?

- ☐ Yes ☐ No (The response to this question has no impact on the review or funding of this application.)

Place this form at the end of the signed original copy of the application. Do not duplicate.

Social Security No. _____

PERSONAL DATA ON PRINCIPAL INVESTIGATOR

The Public Health Service (PHS) has a continuing commitment to monitor the operation of its review and award processes to detect—and deal appropriately with—any instances of real or apparent inequities with respect to age, sex, race, or ethnicity of the proposed principal investigator.

To provide the PHS with the information it needs for this important task, complete the form below and attach it to the signed original of the application after the Checklist. **Do not attach copies of this form to the duplicated copies of the application.**

Upon receipt of the application by the PHS, this form will be separated from the application. This form will **not** be duplicated, and it will **not** be a part of the review process. Data will be confidential, and will be maintained in Privacy Act record system 09-25-0036, "Grants: IMPAC (Grant/Contract Information)." The PHS requests Social Security Numbers for accurate identification, referral, and review of applications and for management of PHS grant programs. Provision of the Social Security Number is voluntary. No individual will be denied any right, benefit, or privilege provided by law because of refusal to disclose his or her Social Security Number. The PHS requests the Social Security Number under Sections 301(a) and 487 of the PHS Act as amended (42 USC 241a and USC 288). All analyses conducted on the date of birth and race and/or ethnic origin data will report aggregate statistical findings only and will not identify individuals.

If you decline to provide this information, it will in no way affect consideration of your application.

Your cooperation will be appreciated.

DATE OF BIRTH (MM/DD/YY)	GENDER
	<input type="checkbox"/> Female <input type="checkbox"/> Male

RACE AND/OR ETHNIC ORIGIN (check one)

Note: The category that most closely reflects the individual's recognition in the community should be used when reporting mixed racial and/or ethnic origins.

- ☐ **American Indian or Alaskan Native.** A person having origins in any of the original peoples of North America, and who maintains a cultural identification through tribal affiliation or community recognition.
- ☐ **Asian or Pacific Islander.** A person having origins in any of the original peoples of the Far East, Southeast Asia, the Indian subcontinent, or the Pacific Islands. This area includes, for example, China, India, Japan, Korea, the Philippine Islands, and Samoa.
- ☐ **Black, not of Hispanic origin.** A person having origins in any of the black racial groups of Africa.
- ☐ **Hispanic.** A person of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin, regardless of race.
- ☐ **White, not of Hispanic origin.** A person having origins in any of the original peoples of Europe, North Africa, or the Middle East.
- ☐ Check here if you do not wish to provide some or all of the above information.